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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/733,302

12/08/2000

Steven R. Cohen

1104-013US01

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28863 7590 05/20/2009  
SHUMAKER & SIEFFERT, P. A.  
1625 RADIO DRIVE  
SUITE 300  
WOODBURY, MN 55125

EXAMINER

RAMANA, ANURADHA

ART UNIT

PAPER NUMBER

3775

NOTIFICATION DATE

DELIVERY MODE

05/20/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

pairedocketing@ssiiplaw.com

<b>Office Action Summary</b>	<b>Application No.</b> 09/733,302	<b>Applicant(s)</b> COHEN ET AL.	
	<b>Examiner</b> Anu Ramana	<b>Art Unit</b> 3775	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 March 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-21, 24-28 and 42-48 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21, 24-28 and 42-48 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 March 2009 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Drawings***

The drawings are objected to because the lines and details are unclear. The drawings appear to be copies of originals. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-17, 19-21, 24-28 and 42-48 are rejected under 35 U.S.C. 102(e) as being anticipated by Sellers (US 6,423,069).

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Sellers discloses a tissue distraction device including: a proximal foot plate 14 or first transmitting means constructed of a bioabsorbable material; a distal foot plate 16 or second transmitting means constructed of a bioabsorbable material; an expansion means including a lead screw 102, and outer sleeve 202 and an inner sleeve 302; a first flange 182 that engages a first slot or first flange engagement structure 142 of the first transmitting means; a second flange 220 that engages a second slot or second flange engagement structure 162 of the second transmitting means wherein after distraction is complete, the entire activation portion of the device (lead screw, sleeves, and fasteners) is removed, i.e., the first and second flanges are removed (Figs. 1-3, 4A, 5A, 6A, 7A, 9 and 10, col. 5, lines 57-67, cols 6-9 and col. 10, lines 1-37).

Sellers also discloses the use of screws 18, made of bioabsorbable material, to attach each of the foot plates to bone (col. 10, lines 3-12).

Claims 1-21 and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by Landsberger (US 6,113,599).

Landsberger discloses a distraction device including: a first anchor plate or first transmitting means 411 made of bioresorbable material, the first anchor plate having structure for attachment to bone, i.e., fingers; a second anchor plate or second transmitting means 440 made of bioresorbable material, the second anchor plate having structure for attachment to bone; an expansion means or flexible shaft 402 not integral with the first and second plates including an activation means or hex driver: a screw-actuated expansion mechanism (420, 421); and bioresorbable screws for attaching each of the plates to bone (Fig. 4B, col. 14, lines 26-67, col. 15, lines 1-27, col. 17, lines 29-51, and col. 18, lines 16-31, ).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sellers (US 6,423,069) in view of Williams et al. (US 6,548,569).

Sellers discloses all elements of the claimed invention except for the expansion means to be made at least in part of a biodegradable or a bioabsorbable material.

It is well known in the art to coat implantable devices with a biodegradable coating to enhance the biocompatibility of the device, as evidenced by Williams et al. (col. 4, lines 20-46).

Therefore, it would have been recognized by one of ordinary skill in the art at the time the invention was made, that applying the known technique of providing a biodegradable coating, as taught by Williams et al., to the Sellers device would have yielded predictable results, i.e., enhanced biocompatibility of the device.

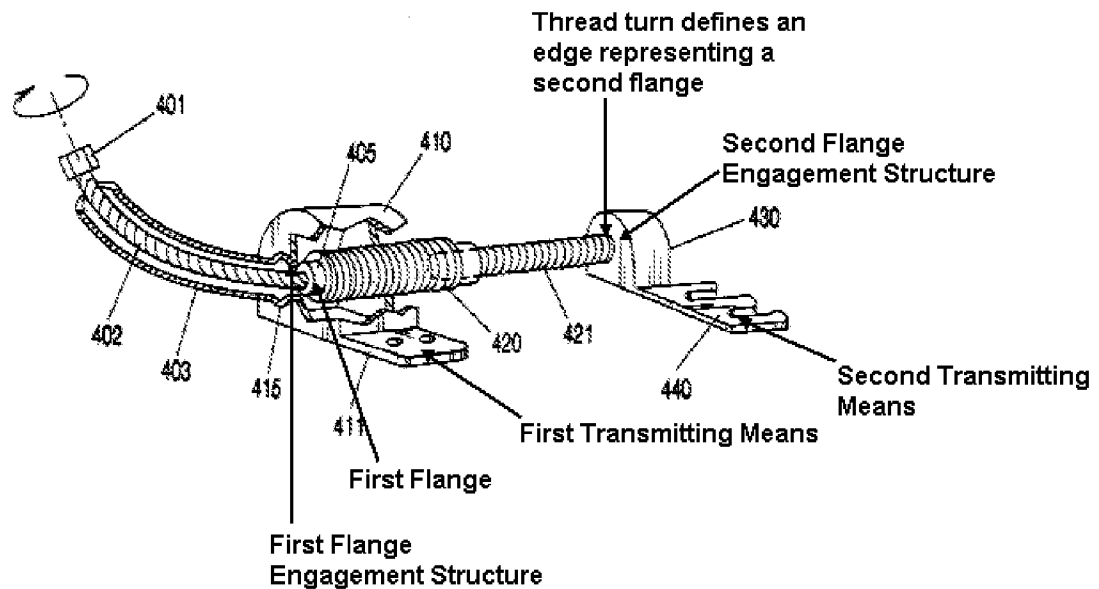
***Response to Arguments***

Applicant's arguments filed on March 9, 2009 have been fully considered by the examiner. Applicant's amendments overcome the rejections under 35 USC 112 second paragraph made in the previous office action.

Applicant's arguments with respect to the rejections over Landsberger are not persuasive for the following reasons. As illustrated in marked up Fig. 4B on the following page, Landsberger discloses the first transmitting means to have a first flange engagement structure, the second transmitting means to have a second flange engagement structure, and the expansion means to have a first flange 405 that

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engages the first flange engagement structure and a second flange that engages the second flange engagement structure.



Landsberger also discloses that the flexible shaft and the flexible sheath are removed after distraction is complete (col. 18, lines 26-29). Thus, the rejections under 35 USC 102(e) over Landsberger are deemed proper.

### **Conclusion**

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (571) 272-4718. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas Barrett can be reached at (571) 272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AR  
May 17, 2009

/Anu Ramana/  
Primary Examiner, Art Unit 3775